

**510(K) SUMMARY**  
**(as required by 807.92(c))**

K970185  
P1/2

**Submitter of 510(k):** Contour Fabricators, Inc.  
4100 East Baldwin Rd.  
Grand Blanc, MI 48439

Phone: (810)695-2910  
Fax: (810)695-5336

APR 10 1997

**Contact Person:** Michael W. Czop

**Date of Summary:** April 3, 1997

**Trade Name:** Sterile, Disposable Magnet Cover

**Classification Name:** Sterile, Disposable Equipment Cover

**Predicate Device:** Contour Fabricators, Inc. Bandbag, Wrap, Sterile, Disposable  
Flouroscope and General Equipment Cover. K782155

Bemiss-Jason Corporation (originally Triad Medical Division), E-  
Z Fit Cover. K831287

**Device Description:** The sterile, disposable magnet cover utilizes a Dexter Nonwoven:  
a soft, strong absorbent pinhole resistant base fabric, which has  
been coated with .5 mil of linear low density polyethylene  
extrusion. The material is blue in color, cut to an overall length  
and width of 114" x 54", and is 5 mils thick.

Through the use of pressure sensitive adhesive tape, the cover can  
be attached to a clean, dry surface to establish a barrier.

**Performance Standards:** Flammability:

Material was tested for flammability in accordance with 16 CFR  
1610. Because the material is disposable in nature and would not  
withstand the rigors of washing and dry cleaning specified by the  
standard, the material was tested in its "as received condition."  
The average rate of burn for the material was 7.3 seconds,  
compliant with Class I flammability standards.

Grammage (Basis Weight): g/m <sup>2</sup>		69.4
Tensile Strength, Dry: g/25mm	MD	3500
	CD	2100
Absorbency (Water Drop): sec		2.5

**510(K) SUMMARY**  
(as required by 807.92(c))

K970185  
PZ/12

**Performance Standards:**  
(Continued)

**Resistance to fluid penetration:**

An engineering test was prepared to determine the ability of the material to resist fluid penetration. Material was subjected to fluid-depth-related pressure of .22 psi for 6 hours, visual and tactile inspection revealed no fluid penetration through the material.

**Intended Use:**

Magnetic Resonance Imaging (MRI) technology requires the use of large magnets for image generation. This technology is now being tested for use in surgical procedures. The sterile, disposable magnet cover is intended to protect the walls of a magnet from gross contamination and also to isolate the sterile field from microbial contamination.

This particular cover is specifically intended for use with the General Electric Medical Systems Signa SP MRI system.